

**REMARKS/ARGUMENTS**

**I. The Response and Status of the Claims**

This response is filed pursuant to 37 C.F.R. § 116, in response to the Office Action dated November 19, 2003. Claims 1-28, 30, 34, 36-83 and 173-196 are pending. Claims 1, 30 and 34 are independent.

As recited in the pending claims, each of independent claims 1, 30 and 34 are directed to a method for sterilizing a biological material. These methods include irradiating the biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize the biological material. As recited in each of independent claims 1, 30 and 34, "said effective rate is not constant for the duration of the sterilization procedure."

**II. Claim Objections**

In the Office Action, the Examiner objected to claims 183, 185 and 187 under 37 C.F.R. § 1.75(c). Regarding this objection, the Examiner stated that claims 183, 185 and 187 "recite a dose rate of 'about 2.0 kGy/hr' but all depend from a claim which recites a dose rate of 'about 3.0 kGy/hr'" and, therefore, fail to further limit the subject matter of a previous claim.

In response to this objection, Applicants submit that claims 183, 185 and 187 do properly limit a previous claim and, therefore, this rejection is improper and should be withdrawn. Specifically, claims 183, 185 and 187 each recite that the effective rate "further comprises a rate of about 2.0 kGy/hr." (emphasis added). The claims from which claims 183, 185 and 187 depend, claims 182, 184 and 186, respectively, recite that the not constant, effective rate

"comprises a rate of about 3.0 kGy/hr". Thus, while claims 182, 184 and 186 only require that the not constant, effective rate additionally includes a rate of about 3.0 kGy/hr, claims 183, 185 and 187 further require that the not constant, effective rate includes a rate of about 2.0 kGy/hr. That is, claims 183, 185 and 187 require that the biological material is irradiated at both about 3 kGy/hr and about 2kGy/hr. Thus, claims 183, 185 and 187 do further limit the not constant, effective rate of claims 182, 184 and 186, from which they depend. Therefore, reconsideration and withdrawal of this objection are respectfully requested.

### **III. Rejections Under 35 U.S.C. §§ 102 or 103**

In the Office Action, the Examiner made the following grounds of rejection:

- A. Claims 1, 2, 5, 13-15, 18, 20-22, 25-28, 30, 34, 37, 45-47, 50, 52-54, 57, 60, 68, 70, 73, 75-77, 80-83, 176, and 179 under 35 U.S.C. 102(b) as allegedly being anticipated by Sakai et al.;
- B. Claims 1, 2, 4-8, 14, 19, 21, 22, 25-28, 30, 34, 36-40, 46, 51, 53, 54, 57, 59-63, 69, 74, 76, 77, 80-83, 177, 180, 188-196 under 35 U.S.C. 102(b) as allegedly being anticipated by Chanderkar et al.;
- C. Claims 1, 2, 4-6, 9, 14, 18, 20-23, 25-28, 182, 183 under 35 U.S.C. 102(b) as allegedly being anticipated by Baquey et al.;
- D. Claims 1, 2, 5, 10, 14, 19, 22, and 25-28 under 35 U.S.C. 102(b) as allegedly being anticipated by Field et al.;
- E. Claims 3, 58, 173-175, 177, and 178 under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai in view of Horowitz et al.;
- F. Claims 4, 6, 11, 12, 16, 17, 36, 38, 43, 44, 48, 49, 59, 66, 67, 71, and 72 under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai et al.;
- G. Claims 3, 30, 34, 36-38, 41, 46, 50, 52-61, 64, 69, 73, 75-83, 173-181,

- 184-187 under 35 U.S.C. 103(a) as allegedly being unpatentable over Baquey et al in view of Horowitz et al.;
- H. Claim 24 under 35 U.S.C. 103(a) as allegedly being unpatentable over Baquey et al.; and
- I. Claims 3, 30, 34, 37, 42, 46, 51, 57, 58, 60, 65, 69, 74, 77, 80-83, 173-181 under 35 U.S.C. 103(a) as allegedly being unpatentable over Field et al. in view of Horowitz et al..

As shown herein, the references relied upon by the Examiner fail to teach or to suggest a method for sterilizing a biological material, wherein the rate of irradiation is "not constant for the duration of the sterilization procedure," as presently claimed. Since the references relied upon by the Examiner fail to teach or to suggest this limitation, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

**A. The Rejections Under 35 U.S.C. § 102**

Regarding Sakai et al., Chanderkar et al., Baquey et al., and Field et al., the Examiner contends that as each of these references "discloses that the gamma radiation source is Co<sup>60</sup>, the dose rate is inherently 'not constant for the duration of the sterilization procedure' since Co<sup>60</sup> experiences natural decay over the duration of the procedure, the decay reducing the dose rate." (Office Action at 3-4). Thus, the Examiner has apparently concluded that the term "not constant" recited in each of independent claims 1, 30 and 34, includes variation in the dose rate resulting from natural decay of the source material. Applicants respectfully disagree.

As shown herein, such a definition is not consistent with the originally filed application and, moreover, is not consistent with the plain meaning of the term as used and understood by one of ordinary skill in the art. Therefore, since the references relied upon by the Examiner fail to teach a method for sterilizing a biological material wherein the rate "is not constant for the duration of the sterilization procedure," as presently claimed, the present claims are not anticipated by Sakai et al., Chanderkar et al., Baquey et al., or Field et al. Therefore, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

**1. The Examiner's Definition of "Not Constant" is Inconsistent With the Plain Meaning of the Term as Understood by One of Ordinary Skill in the Art**

In the Office Action, the Examiner asserts that the term "not constant" recited in each of independent claims 1, 30 and 34, includes variation in the dose rate resulting from natural decay of the source material. For reasons set forth below, such a construction is clearly not consistent with the plain meaning of term as interpreted by those of ordinary skill in the art. *See* MPEP § 2111.01 ("When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art.") (emphasis added). To be read as it would be interpreted by those of ordinary skill in the art, the term "not constant" must indicate a variation in the rate of irradiation that is greater than that resulting from natural decay of the source material over the duration of the sterilization procedure.

The references relied upon by the Examiner disclose the following dose rates:

Reference	Recited Dose Rate
Sakai, et al. <sup>1</sup>	3.45 x 10 <sup>4</sup> rad/hr
Chanderkar, et al. <sup>2</sup>	12,500 R/min
Baquay, et al. <sup>3</sup>	2,600 rad/min
Field, et al. <sup>4</sup>	43,000 rad/min

<sup>1</sup> Sakai et al., at page 1131.

<sup>2</sup> Chanderkar et al., at page 284.

<sup>3</sup> Baquay et al., at page 186.

<sup>4</sup> Field et al., at page 91.

Each of the references relied upon by the Examiner employ a <sup>60</sup>Co irradiation source and recite a constant dose rate; no indication or range of variation is disclosed in ANY of the references. Being those of ordinary skill in the art, Sakai et al., Chanderkar et al., Field et al. and Baquay et al., clearly would have recognized the potential for a change in dose rate due to natural decay of the source material, as asserted by the Examiner. Yet, given this, NONE of these references makes any mention of such variations in the disclosure of the dose rate employed. Thus, the references cited by the Examiner show that those of ordinary skill in the art understand a "constant" dose rate to include any variations due to natural decay.

Since, as demonstrated by the references relied upon by the Examiner, the term "constant" includes any variation resulting from natural decay of the source material during irradiation, it follows that the term "not constant," with respect to dose rate, MUST indicate a variation that is greater than that resulting from natural decay of the source material. The

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Examiner's assertion, then, that " the dose rate is inherently 'not constant for the duration of the sterilization procedure' since Co<sup>60</sup> experiences natural decay over the duration of the procedure, the decay reducing the dose rate" is clearly not as this term would be interpreted by one having ordinary skill in the art. The Examiner's definition, then, is clearly inappropriate.

Therefore, the references relied upon by the Examiner fail to teach each and every limitation recited in independent claims 1, 30 and 34, and claims dependent thereon, since they fail to teach a method for sterilizing a biological material wherein the dose rate is not constant for the duration of the sterilization procedure, as presently claimed. The term "not constant," as interpreted by one of ordinary skill in the art, MUST indicate a variation greater than that resulting from natural decay of the source material. Therefore, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

## **2. The Examiner's Definition of "Not Constant" is Inconsistent with the Specification**

In the Office Action, the Examiner asserts that the term "not constant" recited in each of independent claims 1, 30 and 34, and claims dependent thereon, includes variation in the dose rate resulting from natural decay of the source material. For reasons set forth below, such a construction is clearly not consistent with the specification and, moreover, is not consistent with that those skilled in the art would reach. *See* MPEP § 2111 ("During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification;" and "The broadest reasonable interpretation of the claims must also be consistent

with the interpretation that those skilled in the art would reach.") (emphasis added). To be consistent with the specification and the interpretation that those skilled in the art would reach, the term "not constant" must indicate a variation in the rate of irradiation that is greater than that resulting from natural decay of the source material over the duration of the sterilization procedure.

**a. The Examiner's Definition is Not Consistent With the Specification**

As stated in the original specification, "[p]referably the rate of irradiation is constant for the duration of the sterilization procedure." (page 14, lines 10-12). In order for this passage to be consistent with the remainder of the specification, particularly the examples, the term "constant" must be interpreted to include variation(s) in the rate of irradiation resulting from natural decay of the source material over the duration of the sterilization procedure.

For instance, Examples 1-12 of the original specification each relate to the irradiation of biological materials with a  $^{60}\text{Co}$  source at the dose rates shown in the following table:

Example Number	Rate of Irradiation Recited
1, 2 & 10	1 kGy/hr
3, 4, 5, 6, 7 & 8	0.7 kGy/hr
9	0.72 kGy/hr
11 & 12	0.5 kGy/hr

Each of the examples presented in the original specification recites only a single rate of irradiation. According to each of Examples 1-12, the rate of irradiation was "constant" for the duration of the sterilization procedure described therein. The Examiner's definition, *viz.*, that the dose rate from a  $^{60}\text{Co}$  source is necessarily "not constant," renders Examples 1-12 physically impossible, since only a single, constant dose rate is recited in each of Examples 1-12. Thus, as used in the original specification, a "constant"  $^{60}\text{Co}$  dose rate, such as those recited in Examples 1-12, must include any variation resulting from natural decay of the  $^{60}\text{Co}$  source over the duration of the sterilization procedure.

Since, according to the original specification, the term "constant" includes variations in the rate of irradiation resulting from natural decay of the source material over the duration of the sterilization procedure, it follows that the term "not constant" must refer to a change in the rate of irradiation that is greater than that resulting from natural decay of the source material over the duration of the sterilization procedure. Otherwise, any distinction between the two terms is lost and the term "constant" becomes subsumed by "not constant." Where, as here, the original specification distinguishes between "constant" and "not constant" rates of irradiation, such a reading cannot be correct as it is utterly inconsistent with the remainder of the specification and vitiates the term "constant."

Thus, as shown above, the definition of a "not constant" dose rate asserted by the Examiner is not consistent with the originally filed specification. Clearly then, the references relied upon by the Examiner fail to teach a method for sterilizing a biological material wherein



the dose rate is "not constant for the duration of the sterilization procedure," as recited in each of independent claims 1, 30 and 34. Therefore, for at least this reason, independent claims 1, 30 and 34, as well as claims dependent thereon, are not anticipated by the references relied upon by the Examiner.

**b. The Examiner's Definition is Not Consistent With the Interpretation That Those Skilled in the Art Would Reach**

As discussed above, the Examiner's definition of the term "not constant," with respect to dose rate, is not consistent with the interpretation that those skilled in the art would reach. Therefore, for the term "not constant" to be interpreted as asserted by the Examiner, Applicants would have had to define "not constant" in the specification to include variation resulting from natural decay of the source material, since this definition is clearly inconsistent with the interpretation that those skilled in the art would reach. Nevertheless, in order to expedite prosecution, Applicants would be willing to amend the specification to expressly define the term "constant" as including natural decay. For this reason, then, the prior art relied upon the Examiner does not anticipate the pending claims. Therefore, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

**B. The Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected certain claims under 35 U.S.C. § 103 as being obvious over Sakai et al., or Baquey et al. As shown above, these references fail to teach a method for sterilizing a biological product wherein the rate of irradiation is not constant for the

duration of the sterilization procedure. Instead, each of these references discloses methods employing a constant rate of irradiation. Since neither Sakai et al. nor Baquey et al. suggest such a modification, these references fail to render the present claims obvious under 35 U.S.C. § 103.

Finally, the Examiner rejected the certain of the pending claims over one of Sakai et al., Chanderkar et al., Baquey et al., or Field et al., in view of Horowitz. As shown above, these references fail to teach or to suggest a method for sterilizing a biological product wherein the rate of irradiation is not constant for the duration of the sterilization procedure. Instead, each of these references discloses methods employing a constant rate of irradiation. Horowitz is silent with respect to the rate of irradiation and discloses nothing regarding whether the rate is constant or not. Since Horowitz fails to cure the deficiencies of Sakai et al., Chanderkar et al., Baquey et al., or Field et al., these combinations of references fail to render the pending claims obvious under 35 U.S.C. § 103.

In light of the above, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

### **CONCLUSION**

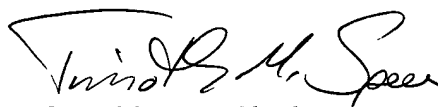
In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned agent, Timothy M. Speer, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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